

## Remarks

### **Introduction**

Receipt is acknowledged of the Office Action dated July 18, 2000. In the Action, the Examiner objected to the specification and claims. The Examiner also rejected claims 1-37 as allegedly indefinite. Finally, the Examiner rejected claims 1-37 for alleged obvious-type double patenting.

By the foregoing, Applicants have amended the specification and claims 1, 2, 18, 19, 24, and 25. Applicants submit that the amendments are mainly formal in nature, requiring no additional search and either place the application in condition for allowance and/or reduce the number of issues on appeal. Support for the amendments is found throughout the original specification and claims. Accordingly, entry of the amendments is respectfully requested. Claim 22 has been canceled and no claims have been added. Consequently, claims 1-21 and 23-37 remain pending for the Examiner's reconsideration. In this regard, reconsideration and withdrawal of the outstanding objections and rejections in view of the foregoing amendments and those remarks set forth below is respectfully requested.

### **Specification**

In paragraph 5 of the Office Action, the Examiner has objected to the specification for allegedly not providing generic terminology for trademarks Onconase or Periamin. However, the present specification provides adequate definitions and descriptions for both of these terms. For example, Onconase is described at page 8, lines 8-11 as "a non-mammalian ribonuclease (RNase) with a molecular weight of 12,000 that can be purified from *Rana pipiens* oocytes and early embryos." Similarly, Periamin is described at page 22, line 5 as "[a] commercially available amino acid solution." Moreover, by the previous response, these terms have been appropriately capitalized. In this manner, the specification sets forth the indicated trademarks in such language that their identity is clear, and the Examiner is respectfully authorized to permit the use of the trademarks since they are adequately distinguished from common descriptive language by capitalization. See M.P.E.P. § 608.01(v). Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection.

In paragraph 6 of the Office Action the Examiner has objected to the Brief Description of the Drawings for allegedly not adequately describing graphs in Figures 2, 4, 6, and 7.

While not acquiescing in the objection, but in the interest of expediting allowance of the application, Applicants have amended the Brief Description of the Drawings in a manner overcoming the objection. Specifically, Applicants have added description for those graphs in the objected Figures as 2A, 2B, 4A, 4B, 6A, 6B, 7A and 7B. The specification has also been amended at those places referring to these Figures. In compliance with 37 C.F.R. § 1.21(a)(3), attached are substitute sheets with the proposed changes in red ink for the Examiner's review. Accordingly, since Applicants have complied with all of the Examiner requirements for the Figures and their description, reconsideration and withdrawal of the objection is respectfully requested.

**Claim Rejections – 35 U.S.C. § 112, second paragraph**

In paragraphs 8 and 9 of the Office Action, the Examiner has rejected claims 1-37 under 35 U.S.C. 112, second paragraph, as allegedly indefinite. Specifically, the Examiner asserts that the term “antibody fragment conjugates” in claims 2 and 22 are indefinite. The Examiner also asserts that the term “onconase” is indefinite in claim 19. Finally, the Examiner objects to those amendments to claims 1, 2, 18, 19, 22, 24, and 25 made in Applicants' response dated April 27, 2000 as written in bold face font. Applicants respectfully traverse the rejection.

With regard to the rejection to claims 2 and 22 over the term “antibody fragment conjugates”, the definiteness of this claim term must be analyzed, not in a vacuum, but in light of the content of the instant application, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary skill in the pertinent art at the time the invention was made. See M.P.E.P. § 2173.02.

First, in relation to above, the term “antibody fragment conjugate” is clear to one of ordinary skill. In this connection, one of ordinary skill would necessarily know what the term means and, therefore, is not indefinite. For example, between the years 1991-1995, which is well before the instant filing date, the term antibody fragment has been recited in over 400 U.S. issued patents. In addition, the term is clearly defined in the specification, which provides nonlimiting examples, namely,  $F(ab)_2$ ,  $F(ab')_2$ , monovalent fragments, e.g., Fab, Fab', Fv, single chain recombinant forms of the foregoing, and the like. Accordingly, Applicants respectfully submit that an “antibody fragment” is not indefinite since one of ordinary skill in the art necessarily would have known what the term meant at the time the invention was made, and since the specification provides a clear definition.

Second, Applicants should not be limited to those terms that are only defined in the claims. The Examiner contends that "the claims define the subject matter of [Applicants'] invention and that the specification cannot be relied upon to read limitations into the claims." However, while Applicants do not deny that it is improper to read limitations contained in the specification into the instant claims, it is, however, almost axiomatic that a claim should be interpreted in light of the specification disclosure. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975) (emphasis applied). Here, if properly read in light of the specification, all of the claims, including those that recite the instant "antibody fragments", are clear to one of ordinary skill, since the specification, *inter alia*, specifically provides an appropriate definition for this term. Therefore the claims are not indefinite in view of the supportive description in the specification and the common interpretation of those of ordinary skill. Accordingly, reconsideration and withdrawal of the rejection respectfully is requested.

Respectfully, Applicants observe that the Examiner's comments in paragraph 8(b) of the Office Action regarding onconase are directed to claim 22 since this claim specifically recites onconase. In any event, without acquiescing in the Examiner's statements, Applicants have canceled claim 22 in the interest of expediting prosecution, thereby obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants appreciate the Examiner's comments in paragraph 9(a) regarding those bolded amendments to claims 1, 2, 18, 19, 22, 24, and 25 filed in Applicants Reply dated April 27, 2000. In order to clarify the amended claims, and expedite prosecution, Applicants have repeated amendments to claims 1, 2, 18, 19, 24, and 25 in a manner suggested by the Examiner, and without the added material in bold. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

#### **Double Patenting**

In paragraph 11, the Examiner has rejected claims 1-37 under obviousness type double patenting over claims 1-12 of U.S. Patent No. 5,843,894. Applicants respectfully request that the rejection be held in abeyance until allowable subject matter is indicated. At that time, Applicants will consider the filing of a suitable Terminal Disclaimer, should one be needed.

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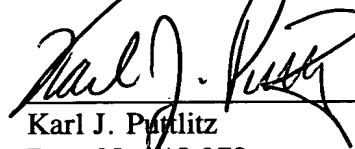
**Conclusion**

In view of the foregoing, it is respectfully urged that the present claims are in condition for allowance. An early notice to this effect is earnestly solicited. Should there be any questions, Examiner Burke is courteously invited to contact the undersigned at the telephone number shown below.

October 18, 2000

Date

Respectfully submitted,



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